IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION | ) | MDL NO. 1203 |
| THIS DOCUMENT RELATES TO: | ) | |
| SHEILA BROWN, et al. | ) | |
| v. | ) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION | ) | 2:16 MD 1203 |

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9054**

Bartle, J. May 2, 2013

Joyce A. Thralls ("Ms. Thralls" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Rodney E. Thralls, claimant's spouse, and Robert H. Czarnecki, Jr., claimant's child, also have submitted derivative claims for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gene E. Myers, M.D. Based on an echocardiogram dated August 12, 1997,[4] Dr. Myers attested in Part II of claimant's Green Form that Ms. Thralls suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Although Dr. Myers indicated that his answers also were based on an echocardiogram dated February 6, 2002, the Trust stated, and claimant did not dispute, that only the August 12, 1997 echocardiogram is at issue in this claim.

regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.[5] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $549,753.[6]

In the report of claimant's echocardiogram, the reviewing cardiologist, John Altieri, M.D., stated that claimant had "[m]ild to moderate mitral regurgitation." Dr. Altieri, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In June, 2006, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram

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5. Dr. Myers also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition is not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

demonstrated only trace mitral regurgitation.[7] In support of this conclusion, Dr. Oliner observed, "Color gain is excessive, with pixelation. There is no [mitral regurgitation] seen in the [parasternal long axis] view."

Based on Dr. Oliner's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, claimant submitted the Verified Statements of Dr. Myers and Arthur McMullen, M.D., F.A.C.C. Both Verified Statements contained the following:

> Four chamber views show mitral regurgitation that is moderate. Subcostral [sic] view also shows moderate mitral regurgitation.
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> Final Assessment:
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> a. Mitral Valve, quality of images is not as good as what we are used to seeing. Images from August 12, 1997 are certainly

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7. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic mitral regurgitation is defined as a "[n]on-sustained jet immediately (within 1cm) behind the annular plane or <+ 5% RJA/LAA."

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

> adequate enough to see that the patient has moderate mitral regurgitation ....

The Trust then issued a final post-audit determination, again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On January 22, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6873 (Jan. 22, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 29, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Thralls made the same argument she made in contest, namely, that the Verified Statements of Dr. Myers and Dr. McMullen provide a reasonable medical basis for the representation of Dr. Myers that Ms. Thralls had moderate mitral regurgitation.

In response, the Trust argues that claimant has not demonstrated a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In particular, the Trust contends that neither Dr. Myers nor Dr. McMullen refute Dr. Oliner's specific finding that the

echocardiogram contained excessive color gain and pixelation. According to the Trust, this manipulation of claimant's echocardiogram has the effect of "inflating, and falsely creating the appearance of, mitral regurgitation."

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante observed:

> I reviewed the Claimant's echocardiogram.... [T]his was a fair quality study with the usual echocardiographic views obtained. However, the color Doppler study was not performed according to the usual standard of care. There was clear evidence of excessive color gain with color artifact noted particularly in the apical views. Color artifact was noted outside of the cardiac structures. In addition, the Nyquist limit was initially appropriately set at 61 cm per second at a depth of 16 cm in both the parasternal and apical views. However, during color Doppler evaluation in the apical view, the Nyquist limit would suddenly be inappropriately lowered to 48 cm per second at a depth of 16 cm. This increased the color artifact noted in the study. In spite of inappropriate color Doppler evaluation, I was able to accurately evaluate the mitral regurgitant jet in real-time.
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> The mitral valve appeared normal with normal leaflet excursion. There was no evidence of mitral valve prolapse nor mitral annular calcification. There was no evidence of mitral regurgitation seen on color Doppler evaluation in the parasternal long axis view. In the apical four and two chamber views, a slightly lateral, small jet of mitral regurgitation was noted just above the mitral leaflet closure point. Visually, only trace mitral regurgitation was present. I

> digitized those cardiac cycles in the apical four and two chamber views in which the mitral regurgitation was best evaluated. I then digitally traced and calculated the RJA and LAA. I determined that the LAA was 18.5 cm2. I was able to accurately determine the RJA in spite of the increased color gain noted on the study. I was able to exclude low velocity, non-mitral regurgitant artifact in the determination of the RJA. The largest representative RJA in the apical two and four chamber views was 0.5 cm2. Therefore, I calculated the largest representative RJA/LAA ratio to be 3%. This qualifies for trace mitral regurgitation. There were no RJA/LAA ratios that came close to 20%. I am unable to determine how Dr. McMullen and Dr. Myers were able to find moderate mitral regurgitation on this study. Even though the subcostal view was a nonqualifying view, I once again noted that trace mitral regurgitation was suggested in that view.
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> ... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, I determined that the echocardiogram of attestation demonstrated trace mitral regurgitation with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.

In response to the Technical Advisor Report, Ms. Thralls argues that Dr. Vigilante inappropriately digitized and measured, rather than eyeballed, claimant's level of mitral regurgitation. In addition, claimant contends, without any medical support, that the machine settings were "obviously" appropriate to "obtain as good an image as possible."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. We disagree with

claimant that the Verified Statements of Dr. Myers and Dr. McMullen provide a reasonable medical basis for the representation of Dr. Myers that Ms. Thralls had moderate mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Oliner reviewed claimant's echocardiogram and determined that "[c]olor gain is excessive, with pixelation." Similarly, Dr. Vigilante reviewed claimant's echocardiogram and observed, "There was clear evidence of excessive color gain with color artifact noted particularly in the apical views."[10]

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10. We also reject claimant's argument that Dr. Vigilante should (continued...)

Dr. Vigilante also noted that there was "increased ... color artifact noted in the study" because of an inappropriately low Nyquist limit. Although Dr. Myers and Dr. McMullen contend the image is adequate enough to determine claimant's level of mitral regurgitation, they do not refute the finding that the echocardiogram had excessive color gain. In fact, they agree that the "quality of [the] images is not as good as what we are used to seeing." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation. To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Thralls for Matrix Benefits and the related derivative claims submitted by her spouse and child.

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10. (...continued)
have eyeballed, rather than digitized and measured, the mitral regurgitation demonstrated on claimant's echocardiogram. In any event, Dr. Vigilante specifically noted, "Visually, only trace mitral regurgitation was present."